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Abstract: Major amputations in patients with peripheral arterial disease (PAD) carry a high risk for complications, including revision of the amputation, sometimes to a higher level. Determining a safe level for amputation with good wound healing potential depends largely on vascular measurements. This study evaluated potential predictive factors for revision of major lower extremity amputations in patients with PAD. A retrospective chart review of all major lower extremity amputations at our institution was conducted. Amputations due to trauma or tumor and below-ankle amputations were excluded. Patient demographics, level/type of amputation, level/time of revision, comorbidities and risk factors were extracted. 180 patients with PAD, mean age 66.48 (range: 31-93) years, 125 (69.4%) male were included. Most (154/180, 86.6%) underwent below-knee amputation. 71 (39.4%) patients had coronary arterial disease, 104 (57.8%) had diabetes. More than half of patients, (93/138; 51.7%) had undergone previous balloon angioplasty. 44 (30%) patients required revision surgery: 42/180 (23.3%) were revised at the same level, and in 12/180 (6.7%) a more proximal amputation was necessary. PAD stage was not associated with the level of reamputation (p = 0.4369). Significantly more patients who had previous balloon angioplasty required revision surgery (66.7% versus 45.2%, p = 0.009). 67 (37.2%) patients underwent preoperative TcPO2 measurement: 40/67 (59.7%) had TcPO2 40 mmHg; 4/67 (6%) had TcPO2 < 10 mmHG. Three patients with TcPO2 40 mmHg, one with 30 mmHg TcPO2 40 mmHg and one with 10 mmHg TcPO2 20 mmHg required re-amputation to a more proximal level. TcPO2 measurements are useful for determining level of lower limb amputation and predicting wound healing problems when an amputation level with TcPO2 < 40 mmHg is chosen. In transtibial amputations, TcPO2 40 mmHg does not safely predict wound healing.

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Original communication

Predictors for reoperation after lower limb amputation in patients with peripheral arterial disease

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Summary: *Background:* Major amputations in patients with peripheral arterial disease (PAD) carry a high risk for complications, including revision of the amputation, sometimes to a higher level. Determining a safe level for amputation with good wound healing potential depends largely on vascular measurements. This study evaluated potential predictive factors for revision of major lower extremity amputations in patients with PAD. *Patients and methods:* A retrospective chart review of all major lower extremity amputations at our institution was conducted. Amputations due to trauma or tumor and below-ankle amputations were excluded. Patient demographics, level/type of amputation, level/time of revision, comorbidities and risk factors were extracted. *Results:* 180 patients with PAD, mean age 66.48 (range: 31–93) years, 125 (69.4%) male were included. Most (154/180, 86.6%) underwent below-knee amputation. 71 (39.4%) patients had coronary arterial disease, 104 (57.8%) had diabetes. More than half of patients, (93/138; 51.7%) had undergone previous balloon angioplasty. 44 (30%) patients required revision surgery: 42/180 (23.3%) were revised at the same level, and in 12/180 (6.7%) a more proximal amputation was necessary. PAD stage was not associated with the level of reamputation ($p = 0.4369$). Significantly more patients who had previous balloon angioplasty required revision surgery (66.7% versus 45.2%, $p = 0.009$). 67 (37.2%) patients underwent preoperative TcPO2 measurement: 40/67 (59.7%) had TcPO2 $\geq$ 40 mmHg; 4/67 (6%) had TcPO2 < 10 mmHG. Three patients with TcPO2 $\geq$ 40 mmHg, one with 30 mmHg $\leq$ TcPO2 $\leq$ 40 mmHg and one with 10 mmHg $\leq$ TcPO2 $\leq$ 20 mmHg required re-amputation to a more proximal level. *Conclusions:* TcPO2 measurements are useful for determining level of lower limb amputation and predicting wound healing problems when an amputation level with TcPO2 < 40 mmHg is chosen. In transtibial amputations, TcPO2 $\geq$ 40 mmHg does not safely predict wound healing.

Keywords: Amputation, revision, level of amputation, peripheral arterial disease, TcPO2, diabetes mellitus

Introduction

In patients with advanced peripheral arterial disease (PAD), amputation is often the last option for treatment of uncontrollable pain or infection. Major amputations in vascular compromised patients carry a high risk for complications, including revision of the amputation, sometimes to a higher level. Across 12 studies, the mean revision rate of 3,454 lower limb amputations was 16.3% (range: 13.4% to 56%) [1–12], with a mean rate of below-knee conversion to a higher level of amputation of 12.9% (range: 0% to 24%).

The healing potential of the amputation wound is severely limited in patients with PAD, due to the reduced perfusion of the area. The healing potential of the wound is better when a more proximal surgery is performed, as proximal perfusion is more likely to be sufficient in these patients or can be improved through percutaneous transluminal angioplasty (PTA) or open vascular surgery [13]. Patients with PAD also usually have numerous comorbidities and risk factors [14], which can influence strategy and level of amputation. If a vascular patient requires amputation surgery due to ischemia of the limb, coronary arterial disease (CAD) should be considered in addition to PAD, and cardiac function should be evaluated [1, 2, 15]. The presence of CAD in addition to PAD is a primary consideration when determining a safe level for performing an amputation with a good healing potential and to avoid major revision surgery [16, 17].

On the other hand, preservation of a major joint leads to a higher probability of ambulation and less energy expenditure [3, 18–21]. Since most vascular patients have severe cardiac and pulmonary limitations as well, a below-knee amputation provides a better likelihood for the patient to resume ambulation.

Given the above considerations, it is understandable why a below-knee amputation would be preferred, if there is a reasonable chance of success. Determining the level of amputation for a patient depends largely on clinical vascular measurements, through both non-invasive and invasive techniques. Simple clinical investigations such as determining capillary refill or taking the pulses of the dorsal pedal and posterior tibial artery may give a first impression of wound healing potential. With structured training, duplex ultrasound is a low cost, reproducible, effective diagnostic tool for detection of PAD [22]. If a diagnosis of PAD has been made, revascularization strategies can be determined based on the location and morphology of the pathology. Ankle brachial index (ABI) and transcutaneous oxygen pressure (TcPO2) are measurements that can predict wound healing potential [23, 24]. In a study by Poredos et al [24], TcPO2 levels > 40 mmHg predicted primary wound healing in 100% of patients, while TcPO2 levels $\leq$ 10 mmHg predicted 0% primary wound healing. For intermediate TcPO2 levels, primary healing rates ranged from 54% for 10–20 mmHg, to 70% for 20–30 mmHg, and 88% for 30–40 mmHg.

The purpose of this study was to determine predictive factors for revision of major lower extremity amputations in patients with PAD and to investigate the effect of preoperative TcPO2 levels on amputation level and the need for revision.

Patients and methods

Study design

We conducted a retrospective chart review of prospectively collected data of all major lower extremity amputations performed at our institution between 2002 and 2016. Our institution specializes in the treatment of patients with diabetes and patients with PAD, poor vascular status or ischemia. The search keyword for the in-house database was "amputation". Exclusion criteria were amputations due to trauma or tumor within 20 cm of the amputation level, primary amputations performed at another institution, and minor amputations (i.e., at or below the level of the ankle) [25], which were all manually subtracted from the primary search result. This study was reviewed and approved by the local research ethics committee, and informed consent was obtained according to the committee's regulations.

Patient demographics and clinical data were derived from the institutional electronic medical records. All data were collected prospectively. In all cases, amputation level was determined by a senior orthopedic surgeon, based on angiologic evaluation, the presence of palpable pedal pulses, TcPO2 values if palpable pedal pulses were absent, sufficient mechanically resilient skin on the lower limb, and the exclusion of alternative treatment options. All amputations were performed by or under the direct supervision of an attending orthopedic surgeon. For TcPO2 measurement, the room-temperature probe was applied at the planned site of amputation, 12 to 15 cm below the knee joint line for below-knee amputations, while the patient was lying flat. Information collected included patient demographic data, level and type of amputation, whether the revision was performed at the same level or a more proximal level, time from amputation to first revision, and presence of polyneuropathy or diabetic nephropathy. For diabetes mellitus, the date of diagnosis, type (1 or 2), duration, and treatment (none, insulin, oral antidiabetic medications) were determined from the medical records. Peripheral arterial disease was graded using Fontaine stages I to IV [26], and it was noted whether ipsilateral PTA or peripheral bypasses were performed prior to amputation. Risk factors including smoking and alcohol use [27] were extracted.

Statistical analysis

Data were analyzed using IBM SPSS Statistics version 20.0 (IBM Corp, Armonk, New York). Differences in categorical variables between patients who underwent revision and those without revision were analyzed using chi-square tests. Differences in continuous variables were analyzed using logistic regression. Differences in PAD stage between patients who underwent revisions at the same level or level above were analyzed using Fisher's exact test. The level of statistical significance was set at $\alpha = 0.05$.

Results

Patient demographics and comorbidities

A total of 182 patients with PAD who underwent major lower extremity amputation between 2002 and 2016 were identified. Two patients were excluded due to missing follow-up data. Of the remaining 180 patients, 125 (69%) were males, with a mean age at first amputation of 65.7 years (range: 32 to 90) (Table I). The 55 females had a mean age of 68.6 years (range: 31 to 93). Mean follow-up was 814 (range: 3 to 4,229) days. 34 patients (18.9%) died during the study period, at a mean of 766 (range: 3 to 3,512) days after the first amputation. The cause of death was related to the underlying severe infection in four patients; the cause of death was not listed in the charts for the remaining 30 patients.

Almost one-half of patients (83/180, 46.1%) had PAD at Fontaine stage IV (Table I). Patients in the early stages of PAD (I and IIa) who required amputation had severe soft tissue infection or osteomyelitis (n = 20), a combination of infection and ischemia (n = 5), or new onset of gangrene (n = 4).

A diagnosis of CAD was recorded for 71 patients (39.4%), and 93 patients (51.7%) had undergone a previous balloon angioplasty. A diagnosis of diabetes mellitus was recorded for 104 (57.8%) patients: 22/104 (21.2%) had type I diabetes and 82/104 (78.9%) had type 2 diabetes. Most of the diabetic patients (70.1%) were taking insulin injections.

Table I. Demographics of patients who underwent major lower extremity amputation (n = 180) and amputation patients who required revision surgery (n = 54).

	All amputation patients (n = 180)	Revision patients (n = 54)	No revision (n = 126)	P-value
Gender: male	125 (69.4%)	41 (75.9%)	84 (66.7%)	0.289[1]
Age, years; mean (range)	66.48 (31–93)	65.58 (35–84)	68.93 (31–92)	0.388[2]
Bilateral amputation	25 (13.9%)	11 (20.4%)	14 (11.1%)	0.106^
Level of amputation or revision:				0.356^
Below knee (i.e., transtibial)	154 (85.6%)	44 (81.5%)	110 (87.3%)	
Above knee (i.e., transfemoral)	26 (14.4%)	10 (18.5%)	16 (12.7%)	
Reason for amputation:				0.201^
Infection	50 (27.8%)	11 (20.4%)	39 (30.9%)	
Gangrene	43 (23.9%)	12 (22.2%)	31 (24.6%)	
Acute ischemia	33 (18.3%)	15 (27.8%)	18 (14.3%)	
Gangrene and infection	27 (15%)	9 (16.7%)	18 (14.3%)	
Osteomyelitis	10 (5.6%)	2 (3.7%)	8 (6.3%)	
Ischemia and infection	4 (2.2%)	2 (3.7%)	2 (1.6%)	
Recurrent foot ulcer	4 (2.2%)	1 (1.8%)	3 (2.4%)	
Other[1]	9 (5%)	2 (3.7%)	7 (5.6%)	
PAD stage[2]				0.231^
No stage assigned	44 (24.4%)	11 (20.4%)	33 (26.2%)	
Stage I	17 (9.4%)	4 (7.4%)	13 (10.3%)	
Stage IIa	12 (6.7%)	0	12 (9.5%)	
Stage IIb	17 (9.5%)	5 (9.3%)	12 (9.5%)	
Stage III	7 (3.9%)	3 (5.6%)	4 (3.2%)	
Stage IV	83 (46.1%)	31 (57.4%)	52 (41.3%)	
Coronary arterial disease	71 (39.4%)	25 (46.3%)	46 (36.5%)	0.246^
Diabetes mellitus	104 (57.8%)	36 (66.7%)	68 (54.0%)	0.139^
Previous balloon angioplasty	93 (51.7%)	36 (66.7%)	57 (45.2%)	0.009^
TcPO2	(n = 67)	(n = 24)	(n = 43)	0.382°
≥ 40 mmHg	40/67 (59.7%)	16/24 (66.7%)	24/43 (55.8%)	
≥ 30 to < 40 mmHg	16/67 (23.9%)	5/24 (20.8%)	11/43 (25.6%)	
≥ 20 to < 30 mmHg	3/67 (4.5%)	1/24 (4.2%)	2/43 (4.7%)	
≥ 10 to < 20 mmHg	4/67 (6%)	2/24 (8.4%)	2/43 (4.7%)	
< 10 mmHg	4/67 (6%)	0	4/43 (9.3%)	
Smoking	(n = 158)	(n = 50)	(n = 108)	0.465^
Never	61/158 (38.6%)	20/50 (40.0%)	41/108 (38.0%)	
Yes – currently	46/158 (25.3%)	17/50 (34.0%)	29/108 (26.9%)	
Former Smoker (date of discontinuation not available)	51/158 (32.3%)	13/50 (26.0%)	38/108 (35.2%)	
Alcohol consumption: yes	83/170 (48.8%)	27/51 (52.9%)	56/119 (47.1%)	0.486^
< 1 glass of beer or wine/day	51/170 (30.0%)	14/51 (25.9%)	37/119 (31.1%)	
1 glass of beer or wine/day	13/170 (7.6%)	6/51 (11.8%)	7/119 (5.9%)	
> 1 glass of beer or wine/day	19/170 (11.2%)	7/51 (13.7%)	12/119 (10.1%)	

[1]Other reasons include: tumor at the level of the foot (n = 3), Charcot neuroarthropathy (n = 2), delayed nonunion after ankle fusion (n = 2), complex regional pain syndrome (n = 1); insufficient bone stock for a fifth revision of total knee arthroplasty (n = 1).
[2]PAD: peripheral arterial occlusive disease. Stages according to Fontaine et al (1954) (26); in 44 patients, no PAD stage was assigned; ^Chi-square analysis; +T-test; ° Logistic regression.

The most common reasons for amputation were infection (27.8%), gangrene (23.9%), acute ischemia (18.3%), and combined gangrene and infection (15.0%) Most patients (154/180, 86.6%) underwent below-knee amputation as the index operation (Table I). 25 patients underwent bilateral amputations.

Patients with PAD who required revision of the amputation were similar to patients with PAD who did not undergo revision for gender, age, level of amputation, reason for amputation, PAD stage, CAD, diabetes, smoking status and alcohol consumption (Table I). Although more patients who required amputation due to acute ischemia subsequently underwent revision (27.8% versus 14.3%) and fewer patients who required amputation due to infection subsequently underwent revision (20.4% versus 30.9%), these differences were not statistically significant (p = 0.201). Significantly more patients with PAD who required revision of the amputation had undergone a

previous PTA compared to patients who did not require revision (66.7% versus 45.2%, p = 0.009).

Revision surgery

54 (30%) patients required revision surgery; 42/54 (77.7%) underwent revision at the same level, and 12/54 (22.2%) required revision to a more proximal level (11 to transfemoral, 1 to through the knee). The mean time from amputation to first revision was 92.7 (range: 5 to 642) days. 10 of 54 patients (18.5%) underwent more than one revision surgery. Three patients underwent two revisions: one patient was converted from transtibial to transfemoral level after 145 days due to skin necrosis and ischemia; two patients were revised at the same level. Seven patients underwent three or more revisions: four with soft tissue infection, two with delayed wound healing, and one with a planned second and third investigation after undergoing amputation due to necrotizing fasciitis; none of these patients were converted to a more proximal level.

The PAD stage was known for 43 of 54 (79.6%) patients who required revision surgery (Table II). Seven of 11 (63.6%) patients with stage I, II, or III PAD and 24 of 31 (77.4%) patients with stage IV PAD underwent revision at the same level (p = 0.4369). One patient who underwent two revisions, first at the same level and subsequently at a more proximal level, was excluded from this analysis. TcPO2 levels 67 (37.2%) of 180 patients in this retrospective study underwent preoperative TcPO2 measurement. Of these, 40 patients (59.7%) had a preoperative TcPO2 $\geq$ 40 mmHg Table I), which is considered the limit above which wound healing can be expected. Interestingly, the four patients with TcPO2 < 10 mmHg did not require revision.

In the 67 patients with preoperative TcPO2 measurements available, 64 (95.5%) underwent below-knee amputation and 3 (4.5%) underwent above-knee amputation (Table III). Twenty-three (35.9%) below-knee amputations required revision, and 1 (33.3%) above-knee amputation required revision.

The overall revision rate was 35.8% for patients with a preoperative TcPO2 measurement compared to 26.5% for patients who had no preoperative TcPO2 measurements (p = 0.239, Fisher's exact test). A single revision was performed in 29.9% of patients with preoperative TcPO2 measurements available and 20.4% of patients without TcPO2 measurements (p = 0.239). Wound revisions were performed in 28.4% of patients with preoperative TcPO2 measurements available and in 16.8% of patients without preoperative TcPO2 measurements (p = 0.088).

TcPO2 measurements were available for 24 patients who required revision surgery. Of these, 16 (66.7%) patients had TcPO2 levels $\geq$ 40 mmHg, 5 (20.8%) patients had TcPO2 levels between 30 and 40 mmHg, 1 (4.2%) patient had TcPO2 levels between 20 and 30 mmHg, and 2 (8.3%) patients had TcPO2 levels between 10 and 20 mmHg. 19 (79.2%) of 24 patients underwent revision at the same level, whereas 5 (20.8%) were revised to the level above (Table III).

Table II. PAD stage and level of revision for patients who underwent reoperation (revision) of lower limb amputation.

PAD stage	Level of revision* Same level (n = 31)
Stage I, II, or III (n = 11)	7 (63.6%)
Stage IV (n = 31)	24 (77.4%)

* One patient underwent 2 revisions, one at the same level and subsequently one at a more proximal level, and was excluded from the table.

Discussion

Determining the level of amputation in the lower limb is a challenge to the treating surgeon. Several elements, such as comorbidities, capability of assimilating additional energy expenditure, and simplicity of seating position, must be considered. In patients with PAD, poor vascular status or ischemia, wound healing potential has a crucial influence on the choice of amputation level. In our study population of 180 patients with PAD who underwent lower limb amputation, 30% required revision surgery, with 6.7% subsequently converted to a more proximal level. Many of these patients also had insulin-dependent diabetes mellitus or CAD.

While many studies have evaluated risk factors for primary lower limb amputation in patients with PAD or critical limb ischemia, the literature on risk factors for revision surgery following primary lower limb amputation is sparse. Wu et al. [28] reported that end-stage renal failure and preoperative non-ambulatory status were independent risk factors for subsequent above-knee amputation in 210 Asian patients with PAD who underwent below-knee amputation. In our study, the only patient factor associated with revision surgery was having undergone a previous PTA (p = 0.009]. Balloon angioplasty is often considered a surrogate indicator of more severe peripheral vascular disease. As such, PTA is typically only performed in clinically critical patients where the surgeon has concerns about the extent of vascular dysfunction, to aid in decision making regarding the level of amputation, and to potentially improve wound healing following amputation as part of the limb salvage procedure.

The overall revision rate of 30% in our study population is lower than the 56% rate observed by Inderbitzi et al in 66 consecutive patients with PAD who underwent bilateral lower limb amputation [1]. While our rate was higher than the mean revision rate of 16.3% observed in 3,454 lower limb amputations across 12 studies [1–12], some of these studies were not limited to patients with PAD and instead consisted of patient populations with no or varied comorbidities [7, 9–11]. In our study, 6.7% of patients who underwent amputation required conversion of their amputation to a more proximal level, which is lower than the mean rate of below-knee conversion to a higher level of amputation of 12.9% (range: 0% to 24%) observed in the other studies [1–12].

Poredos et al. [24] reported that TcPO2 levels > 40 mmHg predicted primary wound healing in 100%

Table III. TcPO2 levels in patients undergoing major lower extremity amputation (n = 67).

TcPO2 level	N	Below-knee amputation (i.e., transtibial)		Above-knee amputation (i.e., transfemoral)
		Total	Revised	Total
≥ 40 mmHg	40	39	16	1
≥ 30 to < 40 mmHg	16	14	4	2
≥ 20 to < 30 mmHg	3	3	1	0
≥ 10 to < 20 mmHg	4	4	2	0
< 10 mmHg	4	4	0	0

of patients in a series of 56 patients who underwent below-knee amputation for ischaemic limb gangrene, whereas TcPO2 levels ≤ 10 mmHG predicted 0% primary wound healing. In our study, three patients with TcPO2 levels > 40 mmHg before the index amputation required reamputation at a more proximal level. In each of those cases, the indication for reamputation was progressive skin necrosis and declining arterial blood supply, as judged by the treating angiologist. Only two patients with a TcPO2-level < 40 mmHg required revision at a higher level in our study. These findings would suggest that determination of TcPO2 levels at the proximal third of the tibia does not safely predict wound healing potential in patients with PAD.

In partial foot amputations, TcPO2 levels were found to be predictive of wound healing potential [24, 29], which indicates its value in decision-making around amputation level when treating patients with diabetes and/or patients with PAD, poor vascular status or ischemia. While the predictive value of TcPO2 levels in our study was not demonstrated, perhaps in part due to the limited number of patients for whom this information was available, we believe that the preoperative measurement of the TcPO2 is still a useful tool to provide objective values for discussion of amputation level with the patient.

Many patients with PAD and/or diabetes have significant comorbidities, particularly coronary heart disease, which limits the physical effort they can undertake following lower limb amputation. A below-knee amputation was undertaken in some patients with low preoperative TcPO2 values to preserve lower limb length and minimize the physical effort required for ambulation. In most of these cases, only minor revisions for wound healing problems were observed. Only one patient required revision at a higher level.

Limitations

Limitations of this study include the retrospective study design, which limited the patient demographic data available for review and may have introduced unintentional bias. Another limitation is the availability of preoperative TcPO2 levels for only a subset of patients in our study who underwent lower limb amputation. TcPO2 is not routinely performed in all patients who are scheduled for amputation at our institution. The results of this and other studies indicate that a prospective study of preoperative TcPO2 measurement of all patients undergoing lower limb amputation is needed to further elucidate its predictive value for reoperation following primary amputation.

Conclusions

In conclusion, PAD stage is not predictive of a need for revision surgery following lower limb amputation. TcPO2 measurements are a useful adjunct tool to determine the level of lower limb amputation and to predict wound healing problems in cases where an amputation level with TcPO2 values below 40 mmHg is chosen. However, in transtibial amputations, values above 40 mmHg do not safely predict wound healing, and both the patient and the treating surgeon should be prepared for reamputation at a more proximal level.

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